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K041503

AUG 1 2 2004

# 510(k) SUMMARY
# 6/04/04
# D.T. Davis Enterprises, Ltd.

## Premarket Notification Summary

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|---|---|
| **Classification Name:** | **Lift, Patient, Ac-Powered** |
| **Regulation Number** | **21CFR 880.5500** |
| **Class II Device** | |
| **Product Code:** | **FNG** |
| **Trade Name:** | **HoverJack™** |
| **Common Name:** | **Air Patient Lift** |
| **Registration #:** | **2531468 (D.T. Davis Enterprises, Ltd.)** |
| **Reason for Submission:** | **New Technology** |
| **510(k) Number:** | **K041503** |
| **Office Correspondent:** | **David T. Davis, President**<br>**D.T. Davis Enterprises, Ltd.**<br>**t/a HoverTech International**<br>**513 S. Clewell St.**<br>**Bethlehem, Pa. 18015**<br><br>**610-694-9600**<br>**800-471-2776**<br>**610-694-9601 (fax)**<br>**hovermatt@earthlink.net** |
| **Predicate Device:** | **Arjo-Century, Inc.**<br>**Saf-Lift/Saf-Kary**<br>**510(k) #926411 1993** |

**Intended Use:**

The HoverJack™ lifts a patient in a supine position, from the floor to the approximate height of a bed for a subsequent lateral patient transfer.

**Description:**

The HoverJack™ is made of four connected nylon air chambers, each measuring 32" x 70". When inflated, each chamber is 7" high. Each chamber has a dump valve for safety purposes. Each of these chambers has an air entry valve through which an external air supply is used to inflate the chamber. The chamber against the floor is to be inflated first, then the other three chambers are inflated, in an upward succession, until the device is fully inflated. When fully inflated, the HoverJack™ feels hard and substantially supports the patient atop it, also providing a surface upon which emergency patient procedures can

be performed, if necessary. Also in an emergency, dump valves are available to use for quick deflation.

The HoverJack™ is constructed using 200 denier Nylon Oxford. Seams are RF welded (heat-sealed) to limit infection control issues. (Details are attached) The bottom of the HoverJack™ has strips of a non-skid material attached for safety purposes. Fill-valves are self-sealing AND have caps that also screw on for additional closure. The HoverJack™ has two patient safety straps to buckle over the patient.

The HoverJack™ does require the use of the Air Supply that is available as a separate unit. The Air Supply is CSA approved, meeting UL Standard #544. This Air Supply is also used to inflate other equipment such as the HoverMatt® which is an optional accessory to the HoverJack™.

**Comparison to Saf-Lift/Saf-Kary:**
**(Currently Penner Patient Care/Superior Series)**

The reason for utilization of both the HoverJack™ and the SL/SK is to lift a patient in a safe, secure manner without risk of injury to the caregiver. While the lift provided by the SL/SK is for the intended purpose of transferring the patient into a bath, the significance is first and foremost for the comfortable, injury-free patient move. Both of these devices require the use of an AC power source. And, both devices are stationary while the lift is being performed.

However, the technology that powers the lift is different with these devices. The HoverJack™ lift is operated via air that inflates four connected chambers beneath the patient. The "energy" source provides the air that provides the lift. The lift of the SL/SK is accomplished by mechanical action, utilizing moving parts. The "energy" literally powers the lift itself.

See attached Matrix of comparisons.

**Non-Clinical, Volunteer, Safety Testing:**

HoverTech International has tested the HoverJack™ on numerous occasions, both in the manufacturer's warehouse setting and in public trade show venues and in a hospital behavioral health department. Findings and feedback from all scenarios have resulted in safety and comfort improvements ultimately ending in the final design of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2004

Mr. David T. Davis
President
D.T. Davis Enterprises, Limited
T/A HoverTech International
513 South Clewell Street
Bethlehem, Pennsylvania 18015

Re: K041503
Trade/Device Name: HoverJack™ Air Patient Lift Device
Regulation Number: 880.5500
Regulation Name: AC-Powdered Patient Lift
Regulatory Class: II
Product Code: FNG
Dated: August 2, 2004
Received: August 4, 2004

Dear Mr. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

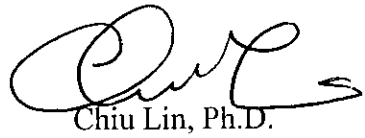
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041503

# Indications for Use

510(k) Number (if known): K041503

Device Name: HoverJack™ Air Patient Lift Device

Indications For Use:

The HoverJack™ lifts a patient in a supine position, from the floor to the approximate height of a bed for a subsequent lateral patient transfer.

Prescription Use ___XX_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Paul R. Blum for ADW August 12, 04

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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